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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,832	12/30/2003	Heinz Redl	20695C-003420US	9378

44183 7590 07/22/2005

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/749,832

Applicant(s)

REDL ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-12 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-33 is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-12 and 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 8, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the recitation of "basic fibrinogen growth factor" in claims 1 and 6. It is possible that Applicants intended to recite "basic fibroblast growth factor".

2. Claim 8 is objected to because of the following informalities: The second period at the end of claim 8 should be deleted. Appropriate correction is required.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3-6, 8, 12, and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No.

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6,506,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '365 patent anticipate the instant claims.

The terminal disclaimer over U.S. Patent No. 6,506,365 referred to in Applicants' remarks was not received by the time it became necessary to prepare this Office action.

5. The effective filing date of instant claims 1, 3-6, 8, 12, and 24 is deemed to be September 25, 2000, the filing date of grandparent application 09/669,240. Instant claims 1, 3-6, 8, 12, and 24 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '240 grandparent application because the '240 grandparent application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

The effective filing date of instant claims 25-33 is deemed to be September 25, 2001, the filing date of parent application 09/963,156. Instant claims 25-33 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/669,240 because the '240 grandparent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a fibrin/fibrinogen-binding moiety which is a nucleic acid, does not disclose a substance capturing moiety which is a receptor or a part thereof, and does not disclose a pharmaceutically active substance which is a wound-healing substance.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 4-6, 8, 12, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (U.S. Patent No. 5,629,287). Brown et al teach fibronectin covalently conjugated to a growth factor binding agent to which is releasably bound a growth factor. The conjugate is used for wound healing. See, e.g., the Abstract; Example 3(3); and claims 1-6.

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8. Claims 1, 4-6, 8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Vogel et al (U.S. Patent No. 5,869,616). Vogel et al teach a fibrin binding domain polypeptide derived from fibronectin covalently conjugated to DTPA to which is bound an imaging agent such as indium-111. See, e.g., the Abstract and Example 8 at columns 38-40.

9. Claims 1, 3-6, 8, 12, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sosnowski et al (U.S. Patent No. 6,613,563). Sosnowski et al teach basic fibroblast growth factor conjugated to a monoclonal antibody which reversibly binds to an adenovirus vector/nucleic acid. The conjugate is used for gene therapy. See, e.g., column 67, line 62 - column 68, line 21.

10. Claims 1, 4-6, 8, 12, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by the Greenberg et al article (Analytical Biochem., Vol. 266, pages 153-164) as evidenced by Claremon et al (U.S. Patent No. 5,019,572). The Greenberg et al article teaches  $\alpha_v\beta_3$  integrin receptors covalently bound to a solid support. The  $\alpha_v\beta_3$  integrin receptors, in combination with the solid support, correspond to Applicants' claimed conjugate. While the  $\alpha_v\beta_3$  integrin receptors of the Greenberg et al article are not bound directly to one another, Applicants' claims do not exclude from their scope the presence of a linking agent. Further, Applicants do not define "conjugate" so as to exclude the Greenberg et al article's means for indirectly binding one  $\alpha_v\beta_3$  integrin receptor to another. Any  $\alpha_v\beta_3$  integrin receptor attached to the solid support of the Greenberg et al article corresponds to Applicants' fibrin/fibrinogen-binding moiety which can be an integrin (see, e.g., page 154, column 1, second paragraph, of the Greenberg et al article). Any other  $\alpha_v\beta_3$  integrin receptor attached to the solid support of the Greenberg et al article corresponds to Applicants' substance capturing moiety capable of reversibly binding to a

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pharmaceutically active substance, which can be a receptor. In the case of the Greenberg et al article, the other  $\alpha_v\beta_3$  integrin receptor covalently bound to a solid support is capable of binding to radioiodinated echistatin (see, e.g., page 155, column 2, last paragraph; page 156, column 1, first paragraph; and Figure 2). Claremon et al teach that echistatin is a platelet aggregation inhibitor (see column 4, lines 29-42), i.e. is a pharmaceutically active substance. The radioiodinated echistatin of the Greenberg et al article also corresponds to Applicants' pharmaceutically active substance which can be an imaging agent.

11. Claims 29-32 are allowed.

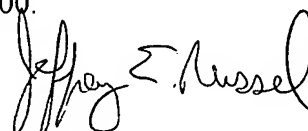
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 19, 2005